September 28, 1998

MEMORANDUM

TO: DEPARTMENT OF HEALTH AND HUMAN SERVICES (HHS)
HHS CERTIFIED AND APPLICANT LABORATORIES
MEDICAL REVIEW OFFICERS (MROs)

FROM: Mary Bernstein, Director
Drug and Alcohol Policy and Compliance Office

SUBJECT: MRO Guidance for Interpreting Specimen Validity Test Results

The Department of Transportation (DOT) regulations (49 CFR Part 40, "Procedures for Transportation Drug and Alcohol Testing Programs") and the Mandatory Guidelines for Federal Workplace Drug Testing Programs published in the *Federal Register* on June 9, 1994 (59 FR 29908) permit laboratories to conduct additional tests to determine the validity of a specimen. In order to provide consistency for such validity tests, the Department of Health and Human Services (HHS) has issued NLCP Program Document (PD) #035 which provides procedural guidance to laboratories for conducting validity tests; defines the criteria for diluted, substituted, and adulterated specimens; and, specifies the language for reporting results to Medical Review Officers (MROs). To complement PD #035, DOT provides guidance through this memorandum on actions that MROs must take in interpreting and reporting laboratory results for all DOT drug tests. We have consulted with HHS and it agrees that this MRO guidance is also applicable to Federal agency workplace drug testing programs.

The Medical Review Officer actions are as follows:

A. Single and/or Primary (Bottle A) Specimens

The Federal CCF requires the MRO to report drug test results as either Negative, Positive, Test Not Performed, or Test Canceled. The MRO must also include an appropriate comment on the "Remarks" line in Step 8 on Copy 2 (required by HHS) or Copy 4 (permissible for DOT) of the CCF when additional information is reported by the laboratory. *Note: Under no circumstances should Copy 2 of the CCF be sent to the employer to report results. The MRO may use a photocopy of Copy 4 of the CCF (assuming that the information on Copy 4 is legible), a memorandum, or a letter format to report a result to the employer.*

The MRO must take the following actions when the laboratory reports:

Negative. The MRO checks the "Negative" box in Step 8 on Copy 2 or Copy 4 of the CCF and reports the result to the employer. If the laboratory also reports that the specimen was dilute, the MRO reports to the employer that the next time the donor is selected for a drug test the employer may require the specimen to be collected under direct observation.

Positive. If the MRO verifies the test as positive, the MRO checks the "Positive" box in Step 8 on Copy 2 or Copy 4 of the CCF, indicates the drug/drug metabolite(s) detected on the "Remarks" line, and reports the result to the employer. If the MRO verifies the test as negative, the MRO checks the "Negative" box in Step 8 on Copy 2 or Copy 4 of the CCF and reports the result to the employer. If the laboratory also reports that the specimen was dilute, the MRO reports to the employer that the next time the donor is selected for a drug test the employer may require the specimen to be collected under direct observation.

Test Not Performed -- Fatal Flaw, _____ (with the flaw stated) or Uncorrected Flaw, _____ (with the flaw stated). The MRO checks the "Test Not Performed" and "Test Canceled" boxes in Step 8 on Copy 2 or Copy 4 of the CCF and enters "Fatal Flaw, _____" (with the flaw stated) or "Uncorrected Flaw, _____" (with the flaw stated), as appropriate, on the "Remarks" line. The MRO reports to the employer that the test is canceled, the reason for cancellation, and that no further action is required unless a negative test result is required (e.g., pre-employment, return-to-duty, follow-up).

Test Not Performed -- Specimen Unsuitable: Cannot obtain valid drug test result. The MRO should discuss the laboratory results with the responsible person or certifying scientist to obtain more specific information. The MRO should then contact the donor and inform the donor that the specimen was not suitable for testing or contained an unexplained interferant. After explaining the limits of disclosure in accordance with HHS guidance or DOT Part 40, as applicable, the MRO should inquire as to medications the donor may have taken. Tolectin® (Tolmetin - a non-steroidal anti-inflammatory medication), Flagyl® (metronidazole - an antifungal and antibacterial agent), and Cipro® (ciprofloxacin - an antibacterial agent) are the most common prescription medications that may interfere with some immunoassay tests.

If the donor gives an explanation that is acceptable to the MRO, the MRO checks the "Test Not Performed" and "Test Canceled" boxes in Step 8 on Copy 2 or Copy 4 of the CCF and enters "Specimen Unsuitable: Cannot obtain valid drug test result" on the "Remarks" line. The MRO reports to the employer that the test is canceled, the reason for cancellation, and that no further action is required unless a negative test result is required (e.g., pre-employment, return-to-duty, follow-up).

If the donor is unable to provide an explanation and/or a valid prescription for one of the above medications, but denies having adulterated the specimen, the MRO checks the "Test Not Performed" and "Test Canceled" boxes in Step 8 on Copy 2 or Copy 4 of the CCF and enters "Specimen Unsuitable: Cannot obtain valid drug test result" on the "Remarks" line. The MRO reports to the employer that the test is canceled, the reason for cancellation, and that a second collection must take place immediately under direct observation.

Test Not Performed -- Specimen Adulterated/Substituted. The MRO checks the "Test Not Performed" box in Step 8 on Copy 2 or Copy 4 of the CCF and enters "Adulterated," or "Substituted," and "Refusal to test" on the "Remarks" line. The MRO reports to the employer that the specimen was adulterated or substituted, either of which constitutes a "refusal to test." The MRO also informs the employer that the right to have the split specimen tested by the donor is withdrawn. Therefore, neither a test of the split specimen, nor a retest of the primary specimen is offered to the donor.

B. Split (Bottle B) Specimens

The Federal CCF requires the MRO to report drug test results as either Reconfirmed, Failed to reconfirm- Both tests canceled, or Test not performed- Both tests canceled. The MRO must also include an appropriate comment on the "Remarks" line in Step 8 on Copy 3 of the CCF when additional information is reported by the laboratory for the split specimen.

The MRO must take the following actions when the laboratory reports:

Reconfirmed. The MRO checks the "Reconfirmed" box in Step 8 on Copy 3 of the CCF and indicates the specific drug/drug metabolite(s) detected on the "Remarks" line. The MRO reports the reconfirmation to the employer and the donor.

Failure to Reconfirm -- Drug/drug metabolite not detected. The MRO checks the "Failed to reconfirm- Both tests canceled" box in Step 8 on Copy 3 of the CCF. The MRO reports to the employer and the donor that both tests must be canceled. Using the "Split Specimen Cancellation Report," the MRO shall inform the Office of Drug and Alcohol Policy and Compliance of the failure to reconfirm.

Failure to Reconfirm -- Specimen Adulterated/Substituted. The MRO checks the "Failed to Reconfirm" box, lines through the accompanying phrase "Both tests canceled," and enters "Adulterated," or "Substituted," and "Refusal to test" on the "Remarks" line in Step 8 on Copy 3 of the CCF. The MRO reports to the employer and the donor that the specimen was adulterated or substituted, either of which constitutes a "refusal to test." Therefore, "refusal to test" becomes the final, single result for both tests.

Test Not Performed. The MRO checks the "Test not performed- Both tests canceled" box in Step 8 on Copy 3 of the CCF and provides the reason for the test not

being performed on the "Remarks" line. The MRO reports to the employer and the donor that both tests must be canceled and the reason for cancellation. In an effort to resolve the discrepancy created by a positive "A" specimen and the inability to test the "B" specimen, the MRO shall order an immediate collection of another specimen from the donor. The MRO shall inform the employer that no advanced notice should be given to the employee of the collection requirement, until immediately before the collection. Using the "Split Specimen Cancellation Report," the MRO shall inform the Office of Drug and Alcohol Policy and Compliance of the test not performed.

This memorandum supersedes and replaces DOT Memorandum, "Reporting of Drug Test Results: Abnormal Test Results and Analysis for Presence of Adulterants," dated December 7, 1993, and should be used in conjunction with HHS PD #035 ("Guidance for Reporting Specimen Validity Test Results").